MINISTRY OF HEALTH

[redacted]

Madrid, January 31, 2025

Dear Mr[redacted]

Thank you for contacting the Ministry of Health to share with us your concerns regarding the COVID-19 modified mRNA vaccine.

The review and analysis of safety data from more than 13 billion doses of COVID-19 vaccines administered worldwide indicates that these vaccines have a favourable safety profile, with benefits outweighing potential risks.

Ongoing evaluation of safety data from mass vaccination campaigns over three years has not identified any link between vaccination and cancer or infertility.

In order to initiate a specific assessment of a possible causal association between a drug and an adverse event, it is necessary to have scientific evidence. That is, information from one or more sources that is sufficiently credible to justify actions aimed at verifying it.

To date, there have been no findings suggesting that COVID-19 vaccines may cause fertility problems or increase the risk of cancer, and therefore no further safety investigations are considered necessary in these areas.

The use and safety of all medicines, including COVID-19 vaccines, is monitored at European level, following the channels established in national and European pharmacovigilance legislation. All countries of the European Union (EU) participate in the evaluation of the safety of medicines through the European Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA).

Once a medicine has been authorised for use in the EU, the EMA and EU Member States continuously monitor its safety and take the necessary administrative measures to protect the health of patients.

Medicines safety surveillance consists of a series of activities to identify and assess the emergence of new risks or changes in existing risks. Suspected adverse reactions reported by patients and healthcare professionals, as well as those identified in new clinical studies or published in the scientific literature, are continuously collected and analysed. On the other hand, safety reports submitted by marketing authorisation holders are periodically evaluated and include all the updated safety information generated worldwide, including an assessment of the benefit-risk balance of the medicinal product. In addition, the results of the post-authorisation safety studies established as a requirement at the time of authorisation are analysed.

Finally, the European Commission, as an EU institution, also plays an important role in the process of assessing the risks of medicines. The Commission adopts a decision that is binding for all EU Member States based on the scientific assessment carried out by the PRAC. That is, the PRAC assesses and issues recommendations on the safety of medicines and the European Commission adopts the final decision to be binding in all EU countries.

Additionally, due to the COVID-19 pandemic, European pharmacovigilance systems were reinforced, implementing intensive monitoring of the adverse events reported following vaccination globally.

In conclusion, with the current data, no findings have been found to suggest that COVID-19 vaccines may cause fertility problems or increase the risk of cancer. Pharmacovigilance systems continue to collect and analyse information to improve knowledge of the safety profile and ensure that the benefits outweigh the risks.

Receive a cordial greeting,

Monica Garcia Gomez

Bibliografía

1.- Wang C, Wang M, LI G, Son, Xing Q, Cao Y Effects of COVID-19 vaccination on human fertility: a post pandemic literature review. Ann Med. 2023 Dec;55(2):2261964. Doi:10.1080/07853890.2023.2261964. -Epub 2023 Sep 27. PMID: 37756386; PMCID:PMC10538453) https://pmc.ncbi.nlm.nih.gov/articles/PMC10538453/

2.- Zace D, La Gatta E, Petrella L, Di Pietreo ML. The impact of COVID-19 vaccines on fertility: A systematic review and meta-anlysis. Vaccine. 2022;40(42). Doi.10.1016/j.vaccine.2022.09.019 https://pubmed.ncbi.nlm.nih.gov/36137903/

3.- Wenzel E, De Paula GG, Jaeger ACS, Müller AK, Benati IF, Da Costa Linn TB, Da Rosa TS, Bouvier VDA, da Rosa RL, Cunha-Filho JS. Impact of COVID-19 vaccination on female fertility. Reprod SCI. 2024 Dec;31(12):3913-3918. Doi:10.1007/s4032-024-01717-2. PMID:39419928. https://pubmed.ncbi.nlm.nih.gov/39419928/

4.- European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) Module IX-Signal management (Rev1). London: EMA; 2017. Disponible en: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-ix-signal-management-rev-1_en.pdf

5.- Real Decreto 577/2013, de 26 de julio, por el que se regula la farmacovigilancia de medicamentos de uso humano. https://www.boe.es/buscar/doc.php?id=BOE-A-2013-8191

6.- European Medicines Agency. Safety of COVID-19 vaccines (internet) Disponible en: https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines